

REMARKS

Claims 1-21 and 24-53 are currently pending and stand rejected. Applicants thank Examiner Woo for extending the courtesy of a telephone interview to Applicants' undersigned attorney and William C. Geary on January 30, 2009. Independent claims 1, 5, 24, 34, and 53 were discussed and agreement was reached that claim amendments of the type made herein to claims 5, 24, 34, and 53 distinguish over all cited art. Claim amendments of the type made herein to claim 1 were discussed as distinguishing over the art, but no agreement was reached regarding particular wording for the amendment.

Claim Amendments

Applicants amend independent claim 1 to recite that the second engaging device is hingedly pivotable relative to a long-axis of the elongated member. Support for this amendment can be found throughout the specification and in the drawings, for example at page 36, lines 25-30 of the application.

Applicants amend independent claim 5 to recite an elongated member having an inner tubular member and an outer tubular member disposed around the inner tubular member. A first tissue engaging device is disposed on one of the inner and the outer tubular member and a second tissue engaging device is disposed on one of the inner and the outer tubular member. Support for this amendment can be found throughout the specification and in the drawings, for example at page 36, lines 17-28 of the application.

Applicants amend independent claims 24 and 53 to correct typographical errors by changing the word "dependent" to "independent."

Applicants amend independent claim 34 to recite an apparatus having an elongated member and first and second movable members positioned at different locations on a long-axis of the elongated member. Support for this amendment can be found throughout the specification and in the drawings, for example at page 36, lines 17-28 of the application. No new matter is added.

Claim Rejections Pursuant to 35 U.S.C. §112

Claims 26 and 28 are rejected pursuant to 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner argues that “the specification does not describe a corkscrew element or a suction device as part of first and second securing parts, which are parts of first and second members operatively linked by an actuating mechanism which facilitates simultaneous dependent movement of the first and second members.” Applicants have amended claim 24, from which claims 26 and 28 depend, to correct a typographical error which recited “dependent movement” rather than the “independent movement” clearly described in the specification. Thus, as agreed in the interview, the rejection pursuant to 35 U.S.C. §112 is obviated.

Claim Rejections Pursuant to 35 U.S.C. §102

Wilk

Claims 1-3, 5-7, 9, 17, 18, 20, 24, 25, 27-30, 45, and 49-51 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,395,367 of Wilk.

Independent Claim 1

Independent claim 1, as amended, recites a tissue shaping instrument having an elongated member with a first tissue engaging device and a second tissue engaging device in which the second tissue engaging device is hingedly pivotable relative to a long-axis of the elongated member. As agreed in the interview, Wilk does not teach or suggest a tissue engaging device that is *hingedly* pivotable relative to a long-axis of the elongated member. Instead, Wilk teaches that tissue engaging devices (34a, 35a, 36a) are disposed at the distal ends of flexible cannulas (34, 35, 36). Thus, while the cannulas may be bendable, solely as a result of a property of the material from which they are made, there is no structure or portion of the cannulas that would enable the tissue engaging members to be *hingedly* pivotable relative to their respective long-axes.

Accordingly, claim 1, as well as claims 2, 3, 45, and 49-51 which depend therefrom, distinguish over Wilk and represent allowable subject matter.

Independent Claim 5

Independent claim 5 recites an elongated member having an inner tubular member and an outer tubular member disposed around the inner tubular member. A first tissue engaging device is disposed on one of the inner and the outer tubular member and a second tissue engaging device is disposed on one of the inner and the outer tubular member. As agreed in the interview, Wilk does not teach or suggest such a configuration. The tissue engaging devices 34a, 35a, 36a of Wilk are each clearly disposed on cannulas 34, 35, 36 respectively, which extend through the outer cannula 32. There are no tissue engaging devices *disposed on* the cannula 32 and thus Wilk cannot meet the requirements of claim 5. Accordingly, claim 5, as well as claims 6, 7, 9, 17, 18, and 20 which depend therefrom, distinguish over Wilk and represent allowable subject matter.

Independent Claim 24

Independent claim 24 recites an apparatus having an actuating mechanism operatively linking first and second members to facilitate simultaneous independent movement of these members. As agreed in the interview, Wilk does not anticipate claim 24 because Wilk fails to teach or suggest an actuating mechanism that both *operatively links* first and second members and that allows *simultaneous independent* movement of first and second members. Wilk discloses separate instruments that are not operatively linked, for example, the separate instruments (34, 35, 36) as shown in FIG. 7 of Wilk. So while these instruments may be considered to be capable of independent movement, they are not operatively linked. In addition, while a single operative tip of Wilk may have two portions which are linked together (i.e., tips (34a) or (36a)), none of the linked tips disclosed in Wilk are capable of simultaneous *independent* movement. Thus, Wilk cannot anticipate claim 24 because Wilk fails to teach or suggest an actuating mechanism that *both* operatively links first and second members *and* allows for simultaneous independent movement of the first and second members. Accordingly, claim 24, as well as claims 25 and 27-30 which depend from claim 24, distinguish over Wilk and represent allowable subject matter.

Kuehn

Claims 34, 35, 37, and 39-44 are rejected pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,695,866 of Kuehn et al. ("Kuehn").

Independent claim 34, as amended, requires an elongated member having first and second movable members positioned at different locations on a long-axis of the elongated member. As agreed in the interview, Kuehn does not teach such a configuration. Kuehn teaches a pair of jaws positioned at the same distal location on the elongate member of Kuehn. Accordingly, claim 34 as well as claims 35, 37, and 39-44 which depend therefrom, distinguish over Kuehn and represent allowable subject matter.

Kortenbach

Claim 53 is rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,086,600 of Kortenbach.

Independent claim 53, as amended, requires an actuating mechanism operatively linking first and second members to facilitate simultaneous independent movement of the members. As agreed in the interview, Kortenbach does not teach such a configuration. In particular, elements 31 and 40 of Kortenbach would never be capable of *simultaneous* independent movement because element 31 cannot be moved without causing movement of element 40. Accordingly, claim 53 distinguishes over Kortenbach and represents allowable subject matter.

Claim Rejections Pursuant to 35 U.S.C. §103

Wilk and McGarry

Claims 4, 10-13, 21, and 31-33 are rejected pursuant to 35 U.S.C. 103(a) as being obvious over Wilk in view of U.S. Patent No. 5,289,963 of McGarry et al. ("McGarry"). Applicants respectfully disagree.

The Examiner states that Wilk discloses the invention substantially as claimed, but fails to

disclose certain limitations as recited in these claims. Thus, the Examiner relies on McGarry to disclose these limitations. McGarry is directed to a surgical stapler having a single stapling device at one end of an elongate member. McGarry, however, fails to remedy the deficiencies of Wilk with regard to independent claims 1, 5, and 24, from which claims 4, 10-13, 21, and 31-33 depend. In particular, McGarry does not teach or suggest a tissue engaging device that is hingedly pivotable relative to a long-axis of an elongated member. In addition, McGarry does not teach or suggest an elongated member having an inner tubular member and an outer tubular member disposed around the inner tubular member and first and second tissue engaging devices each disposed on one of the inner and the outer tubular member, as required by claim 5. Nor does McGarry teach or suggest an actuating mechanism that both operatively links first and second members and allows simultaneous independent movement of the first and second members as required by claim 24. Accordingly, claims 4, 10-13, 21, and 31-33 distinguish over the combination of Wilk and McGarry at least because they depend from an allowable base claim.

Wilk and McPherson

Claims 8, 26, 36, 38, and 52 are rejected pursuant to 35 U.S.C. 103(a) as being obvious over Wilk in view of U.S. Patent No. 5,437,266 of McPherson et al. ("McPherson"). Applicants respectfully disagree.

The Examiner states that Wilk discloses the invention substantially as claimed, but fails to disclose certain limitations as recited in these claims. Thus, the Examiner relies on McPherson to disclose these limitations. McPherson is directed to a surgical retractor having a coiled screw at one end of the device. McPherson, however, fails to remedy the deficiencies of Wilk with regard to independent claims 1, 5, and 24, from which claims 8, 26, 36, 38, and 52 depend. In particular, McPherson does not teach or suggest a tissue engaging device that is hingedly pivotable relative to a long-axis of an elongated member. In addition, McGarry does not teach or suggest an elongated member having an inner tubular member and an outer tubular member disposed around the inner tubular member and first and second tissue engaging devices each disposed on one of the inner and the outer tubular member, as required by claim 5. Nor does McPherson teach or suggest an

actuating mechanism that both operatively links first and second members and allows simultaneous independent movement of the first and second members, as required by claim 24. Accordingly, claims 8, 26, 36, 38, and 52 distinguish over the combination of Wilk and McPherson at least because they depend from an allowable base claim.

Wilk and Kuehn

Claim 14 is rejected pursuant to 35 U.S.C. 103(a) as being obvious over Wilk in view of Kuehn. Applicants respectfully disagree.

The Examiner states that Wilk discloses the invention substantially as claimed, but fails to disclose at least one tissue fixation device that is a two-part fastener. Thus, the Examiner relies on Kuehn to disclose such a tissue fixation device. As noted above, Kuehn is directed to a device for mitral and tricuspid valve repair and fails to remedy the deficiencies of Wilk with regard to independent claim 5, from which claim 14 depends. In particular, Kuehn does not teach or suggest an elongated member having an inner tubular member and an outer tubular member disposed around the inner tubular member and first and second tissue engaging devices each disposed on one of the inner and the outer tubular member, as required by claim 5. Accordingly, claim 14 distinguishes over the combination of Wilk and Kuehn at least because it depends from an allowable base claim.

Wilk and Kammerer

Claims 15 and 16 are rejected pursuant to 35 U.S.C. 103(a) as being obvious over Wilk in view of Kammerer. Applicants respectfully disagree.

The Examiner states that Wilk discloses the invention substantially as claimed, but fails to disclose the limitations of claims 15 and 16. Thus, the Examiner relies on Kammerer to disclose these limitations. Kammerer is directed to an H-type fastener for tissue. Kammerer, however, fails to remedy the deficiencies of Wilk with regard to independent claim 5, from which claims 15 and 16 depend. In particular, Kammerer does not teach or suggest an elongated member having an inner tubular member and an outer tubular member disposed around the inner tubular member and first

and second tissue engaging devices each disposed on one of the inner and the outer tubular member, as required by claim 5. Accordingly, claims 15 and 16 distinguish over the combination of Wilk and Kammerer at least because they depend from an allowable base claim.

Wilk and Yoon

Claim 19 is rejected pursuant to 35 U.S.C. 103(a) as being obvious over Wilk in view of U.S. Patent No. 5,954,731 of Yoon. Applicants respectfully disagree.

The Examiner states that Wilk discloses the invention substantially as claimed, but fails to disclose a viewing endoscope. Thus, the Examiner relies on Yoon to disclose such an endoscope. Yoon is directed to a surgical instrument with multiple rotatably mounted spreadable end effectors. Yoon, however, fails to remedy the deficiencies of Wilk with regard to independent claim 5, from which claim 19 depends. In particular, Yoon does not teach or suggest an elongated member having an inner tubular member and an outer tubular member disposed around the inner tubular member and first and second tissue engaging devices each disposed on one of the inner and the outer tubular member, as required by claim 5. Accordingly, claim 19 distinguishes over the combination of Wilk and Yoon at least because it depends from an allowable base claim.

Wilk and Iacovelli

Claims 46-48 are rejected pursuant to 35 U.S.C. 103(a) as being obvious over Wilk in view of U.S. Patent No. 5,350,391 of Iacovelli. Applicants respectfully disagree.

The Examiner states that Wilk discloses the invention substantially as claimed, but fails to disclose the limitations of claims 46-48. Thus, the Examiner relies on Iacovelli to disclose these limitations. Iacovelli is directed to a laparoscopic scissors device but fails to remedy the deficiencies of Wilk with regard to independent claim 1, from which claims 46-48 depend. In particular, Iacovelli does not teach or suggest a tissue engaging device that is hingedly pivotable relative to a long-axis of an elongated member, as required by claim 1. Accordingly, claims 46-48 distinguish over the combination of Wilk and Iacovelli at least because they depend from an allowable base claim.

Conclusion

In view of the above remarks, Applicants submit that all claims are in condition for allowance, and allowance thereof is respectfully requested.

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